UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DEFENDANT'S FOREIGN DOCUMENTS

I. INTRODUCTION

Defendant act like they have gone far beyond what is typically expected of global pharmaceutical and medical device companies facing products liability claims, by producing 250,000 documents that are located outside the United States (OUS material). However, it is not uncommon for global pharmaceutical or medical device companies to produce many millions of documents or for there to be hundreds if not thousands of depositions. What Defendant has produced in this litigation, approximately 1.5 million documents total,[1] pales in comparison to other pharmaceutical and medical device MDLs. By way of example, in the Vioxx MDL, Merck produced over **fifty million documents**, and there were over **2,000 depositions** before that case settled for $4.85 billion less than 3 years after the JPML conferred MDL status on the Vioxx federally filed lawsuits.[2]

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[1] Ex A - Declaration of Vince Carnevale

[2] Ex B – In Re Vioxx Products Liability Litigation, Order on the Plaintiff Liaison Counsel's Motion for an Award of Plaintiffs' Common Benefit Counsel Fees and Reimbursement of Expenses (Oct. 19, 2010) at 2 and 26.

Moreover, the Vioxx litigation involved just one product at issue whereas the Ethicon MDL involves 11 products: seven products related to the treatment of stress urinary incontinence and four products related to the treatment of pelvic organ prolapse, all of which were designed, developed, tested, manufactured and/or sold to countries outside the United States. To further put Defendant's argument in to perspective, in 2012, "Johnson & Johnson earned $67.2 billion in worldwide sales, an increase of 3.4 percent from 2011. It is a member of the Fortune 100."[3] Moreover, "[w]ith over 27.4 billion in worldwide sales in 2012, [J&J's] [] Medical Devices and Diagnostics (MD&D) business is the largest in the world."[4] The burden and expense of producing the OUS documents requested by the plaintiffs, is a cost of doing business globally, and becoming one of the world's largest pharmaceutical and medical device manufacturers.

More importantly, however, plaintiffs' requests, when considered in light of the global nature of the products at issue, are clearly limited to relevant, non-privileged OUS materials. Specifically, plaintiffs are seeking documents that are relevant to (1) plaintiffs' design defect claims and (2) plaintiffs' failure to warn claims, including but not limited to, materials related to the design of the TVT Family of Products (e.g., Defendant's knowledge of what types of mesh designs would reduce an inflammatory response to the foreign material like, for example, lightweight meshes with small pores), and when Defendant knew or should have known about the frequency and severity of complications associated with their products, what Ethicon did to warn patients and physicians of those complications, what Ethicon did to market their products in light of its knowledge of those complications. In short, the discovery sought of OUS material

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[3] Ex C - Johnson & Johnson Fact Sheet [http://www.jnj.com/sites/default/files/pdf/Johnson-Johnson_Factsheet_May%202013.pdf]

[4] Ex. C – Johnson & Johnson Fact Sheet.

is relevant to plaintiffs' design defect and failure to warn claims, and far outweighs the burden and expense of producing them.

Despite all this, the Defendant is attempting to unreasonably limit the discovery needed for plaintiffs' to effectively maintain their claims. Such an arbitrary limit on discovery would incentivize global companies, like the Defendant here, to hide its dirt outside the borders of the United States. That is why the same argument has been rejected by courts throughout the country, including this very Court where Judge Stanley denied a similar request made by American Medical Systems (AMS). The Defendant should not be permitted to undo Judge Stanley's sound opinion and create an arbitrary shield that would severely limit plaintiffs' ability to maintain their claims against this Defendant simply because the discovery sought is outside of the United States. As Judge Stanley held "it is well-settled that foreign companies related to American domestic companies are subject to production of their relevant documents"[5] And where, as here, the benefit of the production outweighs the burden or expense, the cost will not shift to the requesting party.

II. BACKGROUND

Since the PSC served Ethicon with its First Set of Interrogatories and First Set of Requests for Production on July 25, 2012, the parties have engaged in numerous meet and confers on the issue of OUS document production as well as exchanged numerous emails and written numerous letters on the subject (as required by LR Civ P 37.1(b)). During these

[5] Ex D – Pretrial Order #24 in 2:12-md-2325, 10/30/12, [Doc 326] at 1-2 (hereinafter "PTO #24") (citing *Societe Internationale Pour Participantion Industriales Et Commerciales, SA v. Rogers*, 357 U.S. 197, 205 (1958) (failure to produce records because of fear of punishment under the laws of its sovereign would undermine congressional policies and invite efforts to place ownership of American assets in personal or firms whose sovereign assures secrecy of records); *Tequila Centinela, SA. De C.V. v. Bacardi & Co.*., 242 F.R.D. 1, 12 (D.D.C. 2007) ("the Court is aware of no rule which precludes discovery of ordinarily discoverable materials, solely on the basis that it calls for information outside of the United States or involves facts or activities outside of the United States")).

communications the parties discussed ways to narrow the categories of OUS documents and further refine the production on the issue. During the above mentioned communications with Ethicon, which took place in January and February of this year, the PSC tried to prioritize the production of certain categories of documents and forego certain other productions. As a result, plaintiffs significantly narrowed their request to four discreet areas of concern: testing, manufacturing, design and regulatory issues. Defendant erroneously claim that plaintiffs ignored attempts to schedule the 30(b)(6) deposition of Ms. Downs. However, Defendants fail to tell the whole story. Originally, to further explore the marketing aspect of the OUS document production, Ethicon had offered the deposition of a 30(b)(6) witness on the subject because it believed that the deposition would help the PSC understand the burden of producing these documents. However, the PSC didn't see a reason to move forward with the 30(b)(6) deposition due to the time and expense of conducting such a deposition since the PSC had already agreed to table the production of the vast majority of the OUS marketing documents and advised Ethicon of this in their letter dated April 30, 2013.[6] But as the letter clearly explained, the 30(b)(6) had nothing to do with the outstanding OUS documents being sought and would does nothing to assist us in the present dispute. Following the PSC's letter of April 30, 2013, the PSC was forced to file their Motion to Compel on, *inter alia*, the OUS production. The Court held a hearing on the matter July 17, 2013 following which Ethicon filed its protective order.

Plaintiffs have tailored their requests for documents located outside the United States which are related to: 1) testing; 2) manufacturing; 3) design; and 4) regulatory issues, all of which are relevant to plaintiffs' design defect and failure to warn claims and are reasonably calculated to lead to the discovery of admissible evidence. This is especially so where, as here,

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[6] Ex. E - Letter from Bryan Aylstock to Ben Watson, Esq. (April 30, 2013)

each of the products that are the subject of the litigation were tested, manufactured, designed and/or sold outside the United States.

The original TVT System, for example, was invented by Professor Ulmsten, in Upssala, Sweden who, along with a company he held stock in, Medscand Medical AB, conducted clinical studies of the TVT System in Sweden.[7] Plaintiffs' have evidence that Prof Ulmsten and Medscand's "milestone" payments were contingent upon the successful outcome of clinical studies, which have been used by Ethicon for over two decades to support the safety of the entire line of TVT products.[8] Other non-US Johnson & Johnson affiliated companies have tested TVT, including Ethicon Scotland whose studies revealed that the TVT device is moderately to severely cytotoxic.[9] The Ethicon Scotland studies were never produced to the FDA.

Similarly, the TVT-Obturator System ("TVT-O") was invented, designed and tested by Prof. de Leval in Liege, Belgium.[10] Many of the studies ETHICON relies on for the alleged safety of the TVT Family Products were largely European studies by European doctors, many of whom are Ethicon's paid consultants.

Likewise, Prolift was developed by the "French TVM Group". An employee from Ethicon France, Dr. Axel Arnauld, is the self-proclaimed "inventor" of the Prolift kit. The legal manufacturer of the Prolift Kit is Ethicon Sarl, a swiss company. The clinical trials were conducted by Johnson and Johnson Med. Ltd., a Johnson & Johnson company out of Scotland. The subjects of the study were largely European and European doctors were the lead authors of

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7 Ex F - Deposition of Axel Arnaud, 7/20/13 at 446:23-447:1; 449:23-453:24; 454:24-461:5.

8 Ex F - Deposition of Axel Arnaud, 7/20/13 at 495:1-498:11.

9 Ex G - Summary of Cytotoxicity Testing

10 Ex H – Ethicon Women's Health & Urology, Pipeline Process and Timeline Update, 10/24/07 at slide 9.

the studies. As ETHICON's internal documents demonstrate its Pelvic Mesh products have a "strong heritage of European innovations within EWH&U."[11]

Ethicon's pelvic mesh devices are developed, manufactured and sold throughout the world. As Ethicon states on its own website: "Expanding care globally with offices, R&D Centers and manufacturing facilities in more than 50 countries around the world, our commitment to expanding access to care has never been more far-reaching."[12]

Ethicon is obligated to produce to plaintiffs materials in their care, custody and control that are relevant and responsive to Plaintiffs' RFP's, irrespective of whether they are located in this country or outside of the United States.

III. ARGUMENT

The Defendant does not dispute that the OUS documents plaintiffs are seeking are in Defendant's custody and control. Instead, the Defendant makes the same stale arguments made by AMS that the discovery sought is too burdensome and that before they will produce the requested documents, the plaintiffs should justify a need for the documents being requested.

There is no question that complex litigation in inherently burdensome for all involved, but that does not mean the Defendant can refuse to produce documents that are within their custody and control. As Judge Herndon, who oversees the Pradaxa MDL, reasoned:

> The defendants find this litigation burdensome. It is. It is not unreasonably so given the nature of this endeavor. Would they rather have several hundred different forums, several hundred different judicial opinions, several hundred different lawyers wanting hundreds of depositions of the same witness, and several hundred different places to produce the same several million documents at the same time? The plaintiffs also find it burdensome. They would rather just receive a pot of money without having to litigate. The public would additionally like to know the outcome of this litigation. They, too, find the wait burdensome.

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[11] Ex H – EWH&U, Pipeline Process and Timeline Update at slide 9.

[12] Ex I - Ethicon's website

> Because the defendants present only stale and tired arguments, as this matter was argued fully before the Court on July 9, 2013, because the parties' positions are clear, and because time is of the essence, the Court found no reason to entertain oral arguments. The Court denies the defendants' request for an amendment to CMO 37.

In Re: Pradaxa (Dabigatran Etexilate)Products Liability Litigation, 3:12-md-02385, Order Denying Defendants' Letter Request to Reconsider CMO 37 (7/26/13).

Similarly absurd is Defendant's argument that the plaintiffs must first justify each request for OUS materials. Such a demand is at odds with the discovery rules and Judge Stanley's order in the AMS MDL, where she held that: "AMS's assertion that the plaintiffs should show that they "need" documents in other countries is similarly odd. AMS is the party whose burden it is to produce or make available for inspection and copying its documents which are responsive to discovery requests and otherwise discoverable."[13]

Since the plaintiffs' requests for the production of OUS documents are "reasonably calculated to lead to the discovery of admissible evidence," Defendant's motion – which attempts to block the discovery of documents outside the United States and only serves to needlessly delay the ultimate production of all relevant, responsive documents in this litigation – should be denied.

a. Plaintiffs' Requests for OUS Materials are Reasonably Calculated to Lead to the Discovery of Admissible Evidence.

Rule 26 provides that "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Moreover, Rule 34 governs the production of documents and allows a party to litigation to serve on another party (within the scope of Rule 26(b)) requests:

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[13] Ex D - PTO # 24 at 3.

> (1) to produce and permit the requesting party or its representative to inspect, copy, test, or sample the following items in the responding party's possession, custody or control:
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> a. any designated documents or electronically stored information [in whatever form] … stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form; or
>
> b. any designated tangible things; or
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> (2) to permit entry onto designated land or other property possessed or controlled by the responding party, so that the requesting party may inspect, measure, survey, photograph, test or sample the property or any designated object or operation on it.[14]

There is nothing in Rule 26 or 34 that, on its face, limits its application to documents found only in the United States. *Tequila Centinela, S.A. de C.V. v. Bacardi & Co. Ltd.*, 242 F.R.D. 1, 12 (D.D.C. 2007), "[w]ith regard to the Federal Rules of Civil Procedure, the Court is aware of no rule which precludes discovery of ordinarily discoverable material, solely on the basis that it calls for information outside of the United States or involves facts or activities outside of the United States." The United States Supreme Court also has recognized that Rule 34's control extends to the foreign affiliates of United States domestic corporations because "a finding of lack of 'control' would 'invite efforts to place ownership of American assets in persons or firms whose sovereign assures secrecy of records.'" *Mt. Hawley*, 269 F.R.D at 617 (citing to and quoting *Societe Internationale Pour Participations Industriales Et Commerciales, SA v. Rogers*, 357 U. S. 197, 205 (1958)). *See also Japan Halon Co., Ltd. v. Great Lakes Chemical Corp.*, 155 FRD 626, 629 (N.D. Ind. 1993) (Parties subject to the jurisdiction of courts in the United States should not attempt to "engage [ ] in a species of international hide and seek

[14] Rule 34(1) and (2).

[by not producing documents pursuant to Rule 34];" doing so, could result in sanctions pursuant to Rules 11, 16, and 37.).

Here, Ethicon must produce all documents within its "possession, custody or control" pursuant to Rule 34(1), irrespective of whether those materials are located within or outside the United States. This Court has previously ruled on this very issue and concluded that OUS materials in the care, custody and control of a United States defendant are subject to discovery, and defendants have a legal duty to produce them. Ethicon erroneously implies that Magistrate Judge Stanley's order was limited to the discovery of adverse event information from foreign countries and emails stored on servers outside the United States.[15] This is simply untrue. In no uncertain terms, Judge Stanley ruled: "**[t]o be clear**, AMS conducts business in the United States and in sixty countries; its documents are in the United States and in sixty countries; its relevant and non-privileged documents, wherever they are located, are in AMS's care, custody and control and are discoverable. The Court expects them to be produced, without excessive duplication or unnecessary delay."[16] Judge Stanley's ruling in the AMS matter is consistent with other opinions by this court on this very issue. See e.g., *Mt. Hawley*, 269 F.R.D at 617-619 (a motion to compel the production of documents located in the Ukraine granted where a party located in the United States had control over the materials and where the Court found that the benefits of having the requested documents available outweighed any burden to the party obligated to produce them.). *See also In re Hallmark Capital Corp.*, 534 F.Supp. 2d 981, 982 -

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[15] Defendant Ethicon, Inc.'s Motion and Incorporated Memorandum of Law Supporting Entry of a Protective Order Prohibiting Plaintiffs from Seeking any Further Production of OUS Materials (hereinafter "Ethicon's Motion") [Doc. 699] at pp. 7-8.

[16] Ex D - PTO #24, at 3 (emphasis added); see also *Mt. Hawley Ins. Co.*, 269 F.R.D 609 (Judge Stanley ruled in another case that documents that are in a defendants' possession, custody and control are subject to discovery, regardless of whether they are located in this country or outside the United States).

984 (D.Minn. 2008) (compelling production of documents held in Israel, thereby rejecting the argument of a U. S. citizen that he lacked control over documents in possession of a non-party Israeli partnership of which he was a partner); *In re: Flag Telecom Holdings, Ltd. Securities Litigation*, 236 F.R.D. 177, 180-182,184 (S.D.N.Y. 2006) (American citizen compelled to produce documents in possession of his foreign, non-party corporate employer based on his status as officer); *Addamax Corp. v. Open Software Foundation, Inc.*, 148 F.R.D. 462, 469 (D.Mass. 1993) (non-party subsidiary corporation had "control" over documents in possession of its non-party German parent, and thus subsidiary could be compelled to produce such documents); *M.L.C., Inc. v. N. Amer. Philips Corp.*, 109 F.R.D. 134 (S.D.N.Y. 1986) (documents in possession of non-party\ foreign parent were discoverable from subsidiaries); *Cooper Industries, Inc. v. British Aerospace, Inc.*, 102 F.R.D. 918, 919 (S.D.N.Y. 1984) (wholly-owned subsidiary, which was non-party British parent's distributor and servicer in U.S., was compelled to produce documents in parent's possession).

In fact, the case before the Court now is in many ways even more basic and straight forward than *Mt. Hawley* since Ethicon does not deny that it has full control of the documents in question. Furthermore, there is no legitimate question that responsive, relevant documents are housed overseas. This Defendant's pelvic repair products were implanted in the bodies of women all over the world. Plaintiffs intend to prove that the products were defective and caused serious injuries to many women implanted with these devices both in the United States and in other countries. What the Defendant knew, or what they should have known, about the defective nature of its design or the frequency and severity of the complications associated with their products and what they did to warn patients and physicians will be important issues in this litigation. Defendant's efforts to market and sell their products in foreign countries are likewise

reasonably calculated to lead to the discovery of admissible evidence. Similarly, any information that came to Defendant about their pelvic repair products, including but not limited to information from doctors, patients or medical facilities about product usage and product-related injuries, failures and complications, is directly relevant to this MDL. This is true whether the information came from Europe, Asia, Canada, or from the United States, and is information that will not necessary be contained within the OUS documents produced to date. For example, the French Government released a white paper in 2006 regarding the safety, efficacy, and use of transvaginal mesh.[17] Defendant's knowledge and experience dealing with the fallout of the French report is clearly relevant to the subsequent actions taken – or inactions by Ethicon – in the United States. Similarly, in February of 2011 the Society of Obstetricians and Gynaecologists of Canada released a report questioning the safety and efficacy of transvaginal mesh.[18] Ethicon's worldwide experience to this report - and others like it - also provide notice and knowledge to Ethicon. Finally, Ethicon has a legal duty to report to the Food and Drug Administration ("FDA") adverse events related to their products that occur abroad. 21 CFR § 803. Thus, evidence that Ethicon was not reporting such events or underreporting such events to the FDA is relevant to many of the claims raised by Plaintiffs in this lawsuit, including Ethicon's knowledge of the adverse effects of its products. Decisions not to report adverse events to the FDA, or other foreign entities, will not be contained within the OUS documents produced, including the worldwide adverse event information produced to date. Thus, Plaintiffs submit that documents in the possession, custody and control of Ethicon, both domestically and abroad, must be produced under Rule 34 and this Court's prior holdings.

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[17] Ex J - French Government's 2006 white paper regarding the safety, efficacy and use of transvaginal mesh.

[18] Ex K – 2011 Society of Obstetricians and Gynaecologists of Canada Report on the safety of transvaginal mesh.

b. Claims of Burden Do Not Relieve a Party of Its Discovery Obligations.

Ethicon, in failing to produce the requested documents, argues that compelling them to search for documents housed abroad is unduly costly and burdensome. However, information necessary to enable a party to prepare his case or to facilitate proof at the trial or to expedite progress of the trial, should be produced even though there may be an inconvenience or burden on the party producing them if the benefit to the litigation outweighs the burdens of discovery. *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 207 F.Supp. 407, 409 (M.D.Pa.1962). *See also, U.S. v. American Optical Co.*, 39 F.R.D. 580, 587 (N.D.Cal.1966) ("the fact that the production of documents may involve inconvenience and expense is not alone sufficient reason for refusing discovery which is otherwise appropriate."); *Rockaway Pix Theatre, Inc. v. Metro-Goldwyn-Mayer, Inc.*, 36 F.R.D. 15, 17 (E.D.N.Y.1964) ("all sources of information should be made available regardless of expense...and the mere fact that production would be onerous or inconvenient is not, per se, grounds for denial of a Rule 34 motion."). In fact, as this Court noted in PTO #24, when companies like Ethicon here, "was and is willing to undertake the expense of doing business in sixty countries for the purpose of selling its products; responding to litigation is an expected part of doing that business." [19] Similarly, in *Mt. Hawley*, this Court ruled that although the production of requested discovery would impose a burden on the producing party, the request for discovery was justified in light of the information's relevance and the potential benefits of producing the information.

In this case, it is important that Plaintiffs gain access to the full body of Ethicon's knowledge regardless of whether it is gained through the U.S. experience or abroad. Foreign design decisions, testing of materials and implant techniques are important to the knowledge of

[19] Ex D - PTO # 24 at 5.

Ethicon. Moreover, Plaintiffs need to have basic information to answer questions like: whether U.S. implanting physicians were provided the same information as doctors throughout the rest of the world; whether Ethicon provided different safety or efficacy information to doctors and patients outside the United States from that provided within our borders; whether the same techniques were taught to implant these devices in the United States and outside the United States; whether adverse events from abroad were properly reported to the FDA; and what information Ethicon received from or provided to foreign regulatory bodies compared to what was provided to the FDA.

Thus, Ethicon's excuse that the production of foreign documents is burdensome does not support its failure to comply with Rule 34 and will prejudice plaintiffs' ability to prepare their cases for trial. The foreign documents at issue here are reasonably calculated to lead to the discovery of admissible evidence; much, if not all, of the information to be discovered outside of the United States is likely unavailable from any other source; and any burden to Defendant is outweighed by the benefit to Plaintiffs. Furthermore, Ethicon's proposal that Plaintiffs review the domestic document production and then justify a specific request for particular foreign documents turns discovery burdens and obligations under the Rules on their head. Plaintiffs here have drafted discovery requests that are tailored to obtain documents relevant to the claims in this lawsuit in full compliance with the Federal Rules of Civil Procedure. Then, following several meet and confers on the issue, further agreed to limit their discovery to four discreet areas, and to forego the vast majority of foreign marketing and sales information even though that information could lead to the discovery of admissible evidence. Rule 34 clearly contemplates that Ethicon has an obligation to search for and produce such documents provided that they are responsive and relevant. Nowhere does Rule 34 or any other Rule, for that matter,

suggest that plaintiffs must be placed in the virtually untenable positions where they must first guess, and then prove, that a Defendant has such documents in a particular location before a Defendant is subject to its clear discovery obligations under the Rules. The entire purpose of discovery is to find out what defendant has in its possession, custody and control; to suggest that plaintiffs must assume the burden of figuring out and then proving that such documents exist prior to production is at fundamental odds with the purpose of discovery in the federal courts.

c. Ethicon Should Bear the Costs of Discovery of OUS Materials.

Johnson & Johnson is a multibillion dollar corporation. Just last year, they made over $67 billion in worldwide sales. As Judge Stanley held: "Product liability litigation is a modern day cost of doing business in any nation." [20] Where companies are global manufacturers, the production of millions of documents is is not uncommon. Moreover, where, as here, the OUS materials being sought are critical to plaintiffs' design defect and failure to warn claims, defendants have failed to demonstrate it needs protection from undue burden or expense. As such, as in the AMS matter, defendants' motion for a protective order should be denied.

IV. CONCLUSION

For the foregoing reasons, plaintiffs respectfully request this Court grant their motion to compel and deny in its entirety, Defendant's Motion for a Protective Order.

Respectfully Submitted,

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[20] Ex D – PTO # 24 at 6.

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CERTIFICATE OF SERVICE

I hereby certify that on August 26, 2013, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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